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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/739,881 | 12/18/2003 | James R. Braig | OPTIS.010DV1 | 9775 |

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| EXAMINER | |
|---|---|
| KREMER, MATTHEW J | |
| **ART UNIT** | **PAPER NUMBER** |
| 3736 | |

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|---|---|---|
| | 10/739,881 | BRAIG ET AL. |
| | Examiner | Art Unit |
| | Matthew J Kremer | 3736 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Priority*

1. The Applicant asserts that the present application is a divisional of the parent case 10/015932 ('932). Although the Examiner asserted during prosecution of '932 that certain amended or new claims were not examined because the invention had been constructively elected by original presentation for prosecution on the merits, the examined claims in '932 were drawn to the same embodiment that is claimed in the present application. As a result, the Applicant should have filed the application as a continuation and not a divisional. Applicant should update the first sentence of the specification to properly set forth the relationship with the parent application.

Also, because the examined claims in '932 were drawn to the same embodiment that is claimed in the present application, the double patenting rejections are proper.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,507,288 to Bocker et al. (Bocker). Bocker teaches the step of withdrawing an amount of whole blood from a patient and performing a traditional measurement on the amount

of blood. (column 7, lines 29-40 of Bocker). Bocker teaches the use of thermal gradient inducing elements of a non-invasive blood constituent monitor in the form of LEDs in optical sensor 7, analyzing the blood constituent in blood within the patient by detecting thermal radiation by using light detectors in optical sensor 7, and generating a non-invasive monitor output in the form of output from microcomputer 34. (Fig. 2 of Bocker). Bocker teaches the steps of comparing the non-traditional and traditional output, determining an estimate of error, and correcting the non-invasive monitor output. (column 7, lines 42-64 of Bocker).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,025,597 to Sterling et al. (Sterling) in view of U.S. Patent 5,507,288 to Bocker et al (Bocker). Sterling discloses a noninvasive infrared spectrometer. A temperature gradient is induced and thermal radiation is detected. Sterling does not teach the use of a traditional measurement system that calibrates the measurement. Bocker teaches a system for analyzing a patient's blood concentration of a substance. The system of Bocker includes a non-invasive sensor unit and stationary central unit, which analyzes a

glucose test strip. The patient is able to make a calibration using the glucose test strip 23. (column 7, lines 10-28 of Bocker). Bocker implies that the frequent calibration of the less accurate noninvasive sensors with the highly accurate reagent containing analysis elements allows more accurate measurements without the need of constantly piercing the finger. (column 2, lines 16-27 of Bocker). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sterling to include the calibration method and apparatus of Bocker since the resulting noninvasive measurements will be more accurate. The sensor data and the test strip data are compared and a correction is made from that comparison. (column 7, lines 42-64 of Bocker et al.).

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 13, and 20 of U.S. Patent No.

6,678,542 to Braig et al. (Braig) in view of U.S. Patent 5,507,288 to Bocker et al. (Bocker) and in view of U.S. Patent 6,025,597 to Sterling et al. (Sterling). Claim 1 of Braig claims "a method for calibrating a non-invasive blood constituent monitor connected to a traditional measurement system via a data link...the method comprising...performing a traditional measurement of a blood constituent at the selected measurement location using the traditional measurement system [and] generating a traditional monitor output representing a property of the blood constituent." It is known in the art that the traditional measurement of a blood constituent is withdrawing blood and analyzing the blood using a glucose strip. (column 7, lines 10-28 of Bocker). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the traditional method of measuring a blood constituent as disclosed by Bocker since claim 1 of Braig requires a traditional measurement and Bocker teaches such a measurement. Claim 1 of Braig further claims the steps of placing an "analyzer window of the non-invasive blood constituent monitor in contact with the skin of a patient; analyzing the blood constituent in blood within the patient with the non-invasive blood constituent monitor; and generating a non-invasive monitor output representing the property of the blood constituent." Sterling teaches a noninvasive constituent monitor with an analyzer window that would fulfill the requirement of providing a noninvasive constituent monitor as set forth by claim 1 of Braig. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the noninvasive constituent monitor of Sterling in the claimed device of Braig since claim 1 of Braig requires a noninvasive constituent

monitor with an analyzer window and Sterling teaches one such monitor. Claim 1 of Braig further claims the steps of "comparing the traditional monitor output and the non-invasive monitor output to estimate an error" and "correcting the non-invasive monitor output based on said error". Claim 13 of Braig claims a "method for calibrating a non-invasive blood constituent monitor, the method comprising...performing an invasive measurement of a blood constituent...using an invasive blood constituent monitor; generating an invasive monitor output representing a property of the blood constituent; performing a non-invasive measurement of the blood constituent...using the non-invasive blood constituent monitor; generating a non-invasive monitor output representing the property of the blood constituent; comparing the invasive monitor output and the non-invasive monitor output to estimate an error;" and "correcting the non-invasive monitor output based on said error". As stated above, it would be obvious to use the invasive monitor of Bocker and the non-invasive monitor of Sterling since claim 13 of Braig requires an invasive monitor and a noninvasive monitor and Bocker and Sterling teaches such devices. Claim 20 of Braig claims a method for "calibrating a non-invasive blood constituent monitor, the method comprising...performing an invasive measurement of a blood constituent...using an invasive blood constituent monitor; generating an invasive monitor output representing a property of the blood constituent; performing a non-invasive measurement of the blood constituent...using the non-invasive blood constituent monitor; generating a non-invasive monitor output representing the property of the blood constituent; comparing the invasive monitor output and the non-invasive monitor output to estimate an error; and correcting the non-

invasive monitor output based on said error". As stated above, it would be obvious to use the invasive monitor of Bocker and the non-invasive monitor of Sterling since claim 20 of Braig requires an invasive monitor and a noninvasive monitor and Bocker and Sterling teaches such devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew Kremer
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Art Unit 3736

ERIC F. WINAKUR
PRIMARY EXAMINER